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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/543,025

03/30/2006

Michael Ernest Garrett

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

3771

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/543,025	Applicant(s) GARRETT ET AL.	
	Examiner CLINTON OSTRUP	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-11 are pending in this application.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "high pressure" and "narrow bore" in claims 1-3, 5, and 7 are relative terms. It is unclear how "high" the pressure must be and how "narrow" the bore must be to be included or excluded by the claims. Since these terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1 and 5-11, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Tiep et al (4,535,767) and further in view of Lecourt (6,592,848).

Tiep discloses a nasal cannula (10) that can be used for delivering a breathable gas mixture comprising helium and oxygen to a patient, the nasal cannula (10) comprising a length of high pressure narrow bore tubing (22) having a proximal end region (26) that can be used for connecting to a high pressure source of the breathable gas mixture at a pressure in the range of 100 bar to 300 bar and a distal end region (20) connected to at least one nasal administration device (10), wherein the nasal administration device has at least one orifice (12) that can be used for the expansion of the breathable gas mixture. See: col. 3, lines 35-45 and figures 1-4.

Although Tiep discloses a nasal cannula that is capable of performing the intended use of the apparatus claimed, Tiep lacks the specific teaching of the gases and pressure as claimed.

Lecourt teaches that it is well known to combine helium and oxygen gases together for the treatment of respiratory disorders and teaches that these gases may be packaged between 2 and 300 bar. See: col. 3, lines 43-50 and col. 4, lines 32-45.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the nasal cannula disclosed by Tiep to deliver the gases taught by Lecourt in order to treat the respiratory system of patients with an easy to use nasal cannula.

Regarding claim 5, Tiep discloses the high pressure narrow tube being surrounded by protective sheath (18) or (30). See: figures 1-4.

Regarding claim 6, Tiep discloses a pair of nasal prongs ((32 & 34). See: figure 4.

Regarding claim 7, Tiep discloses an apparatus (10) that can be used for administering a breathable gas mixture of helium and oxygen and discloses a supply tank (col. 3, lines 40-41) as a means for supplying breathable gas at a high pressure and a nasal cannula (10) with a length of high pressure narrow bore tubing (22) having a proximal end region (26) which can be used for connecting a high pressure source of the breathable gas mixture at a pressure in the range of 100 bar to 300 bar and a distal end region (20) connected to at least one nasal administration device (10) , wherein the nasal administration device has at least one orifice (12) that can be used for the expansion of the breathable gas mixture. See: col. 3, lines 35-45 and figures 1-4.

Although Tiep discloses a nasal cannula that is capable of performing the intended use of the apparatus claimed, Tiep lacks the specific teaching of the gases and pressure as claimed.

Lecourt teaches that it is well known to combine helium and oxygen gases together for the treatment of respiratory disorders and teaches that these gases may be packaged between 2 and 300 bar. See: col. 3, lines 43-50 and col. 4, lines 32-45.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used the nasal cannula disclosed by Tiep to deliver the

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gases taught by Lecourt in order to treat the respiratory system of patients with an easy to use nasal cannula.

Regarding claim 8, Tiep discloses pressurized supply tank for administering a gas. See: col. 3, lines 40-41.

Regarding claims 9 and 11, Lecourt teaches that it has been customary to treat patients with 70-75% helium and 20-25 % oxygen, thus teaching the specific percentages of helium and oxygen, as claimed in claims 9 and 11. See: col. 3, lines 43-50.

Regarding claim 10, Lecourt teaches packaging a combination of helium and oxygen at a pressure between 2 and 300 bar. See: col. 4, lines 32-45.

6. Claim 2, as best understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Tiep et al (4,535,767) in view of Lecourt (6,592,848) and further in view of Smart (4,685,456).

The combined references disclose all the limitations of claim 2 except the high pressure narrow tube being coiled.

Smart teaches a self-retracting coiled tube for the delivery of gas to a patient. See: figure 1.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the gas delivery tube of Tiep with a self retracting coiled tube as taught by Smart in order to obtain a nasal cannula with a tube that can be easily expanded and contracted to accommodate a patient's movement.

Regarding claims 3-4, the choice of a known material based on its suitability for the intended use is a design consideration well within the skill of the art.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Miller et al (2002/0178783); Kloeppel (5,865,174); Foss (2004/0089302); Rowland et al (5,099,836); Lundberg (5,832,916; Tiep et al (4,572,177); Jackson (5,513,634); Farr (3,802,431); Stoddard et al (4,953,548).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771